

**American Fresh Juice Council  
4600 Linton Blvd  
Delray Beach FL 33445**

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February 7, 2002

Dockets Management Branch  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane; RM 1061  
Rockville MD 20852

Subject: Comments related to Docket Number CF0161

To Whom It May Concern:

The American Fresh Juice Council (AFJC) appreciates the opportunity to comment on Docket cf0161.

In relation to surface treatments utilized on citrus fruit, FDA recommends that the "treatment be applied to undamaged tree-picked fruit (USDA choice or higher quality). While the AFJC agrees fully with the intent of this recommendation, there is considerable confusion about the USDA Choice grade standard. The AFJC suggests that the FDA revisit this requirement and focus on the original intent of the language. The AFJC suggests that the requirement be modified to read "USDA Choice grade or an equivalent Standard". This will achieve the desired result while providing flexibility to industry.

The AFJC represents primarily small farm family citrus operations in the state of Florida. Some of these small agricultural operations are split into two locations. One part of the business is located adjacent to, or in close proximity to the harvesting. This is typically the location at which the fruit is culled, cleaned, graded and sanitized. Other operations contract with a trusted licensed packinghouse to perform the same function. In either case, the fruit is then transported in sanitary containers to the owner's retail store, where it is extracted and containerized for retail sale. This arrangement is advantageous to the owner for a combination of reasons; two of which are efficiency and compliance with urban regulations. The AFJC sought expert assistance from the Florida Department of Citrus, the University of Florida's Institute of Food and Agricultural Sciences and the Florida Department of Agriculture and Consumer Services to develop a scientifically sound means of complying with the 5-Log reduction requirement of the FDA Warning Label Rule. A Guidance Document was published jointly between the FDOC and UF-IFAS to assist small producers in complying with this rule. This document has enhanced the safety of this category. Additionally, these Florida businesses are required by state

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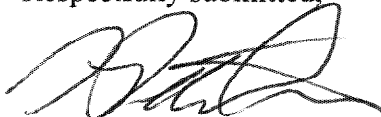
rule to conduct regular microbiological tests for an indicator organism (Ecoli), and FDACS conducts more stringent tests two or three times annually. These Florida facilities are inspected by the state 2-3 times annually and monthly audits of food safety records are conducted. The AFJC knows of no safety related problems with these businesses. Furthermore, while the AFJC believes that previously mentioned guidance documents (to assist small operations in complying with the Warning Label Rule) are valid and effective, it recognizes FDA's intent to disallow the inclusion of 5-log reduction steps separated by time and distance. FDA wishes that each step be achieved within the sole control of one firm and within one facility. This change presents monumental challenges to many small and very small businesses. In recognition of this change in position, the AFJC requests ample time for small businesses to adapt to this change. Many will simply find it impossible to comply, and will exit the business. Others will need time to verify the efficacy of treatment alternatives. Very small producers must find a means of achieving the 5-log reduction without benefit of traditional fruit processing lines and chemical applications. Florida producers will seek assistance from industry sources, but will need time to conduct tests and document results.

**Summary:**

The American Fresh Juice Council has no issue with eliminating steps taken to reduce bacterial load during growing and harvesting from inclusion in a 5-Log reduction calculation. Furthermore, while the Council does not endorse FDA's intent to tighten cumulative 5-log reduction standards for citrus juice producers seeking surface decontamination, it recognizes the momentum toward this end. The AFJC requests sufficient time for small citrus juice producers to develop and adapt appropriate measures to meet this more onerous standard. Because there is not an exemption for pure retail producers within the Warning Label Rule, it affects more small and very small businesses than does the Juice HACCP Rule. Accordingly, the time allotted for small and very small businesses to comply with this latest revision to the 5-log reduction standard should be no less than provided for compliance with the Juice HACCP Rule (from date of publication to date of effectiveness). This new requirement will be a significant change for these businesses.

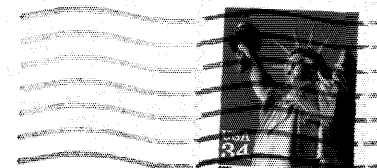
Thank you again for this opportunity to offer comment on this draft guidance.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'J. Peter Chaires', written over a horizontal line.

J. Peter Chaires  
President  
AFJC

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